



# ISO 9001 Overview and Guidance

This guidance document provides an overview of the **ISO 9001:2015 Quality Management Systems** standard.



## Introduction

**ISO9001:2015 Quality Management Systems** is the most recognised international quality standard in the world and is adopted by thousands of organisations. Many companies use **ISO9001** as a framework for ensuring quality within their organisation and they also may achieve certification to show customers and other interested parties that they are meeting the requirements of this standard.

The standard promotes the framework known as **Plan-Do-Check-Act** which should guide the general approach companies take to ensure compliance. Although this concept isn't a specific clause within the standard, it guides the general way of thinking when operating ISO-compliant management systems.



The standard includes a number of clauses based around the general principles outlined in the standard which include:

- **Customer Focus** – ensuring customers are appreciated and treated well is of great importance
- **Leadership** – company management are fully committed to the principles detailed in the quality management system (QMS)
- **Engagement of People** – having effective processes in place to engage with all relevant interested parties
- **Process Approach** – taking a systematic approach when planning and managing operations to ensure consistency
- **Improvement** – commitment to continual improvement of the quality management system and to achieve quality objectives
- **Evidence-based decision making** – critical decisions for the business are based on objective evidence
- **Relationship Management** – commitment to ensuring relationships with all interested parties are effectively maintained and positive

There is no requirement to prepare documentation relating to every clause in the standard or procedures based on these principles, in fact there is nothing in the standard that states you need to have a documented quality manual.

There are some documentation requirements however, an overview of some of the key processes should be documented and you'll need to have a quality policy and there are some requirements relating to the retention of key records. The full standard should be reviewed and

a documentation checklist can be completed to ensure all documentation requirements have been met.

Although there is no requirement to have a documented management systems it's still a good idea to prepare documentation that provides an overview of key processes relating to quality. This documentation is useful in helping everyone within the organisation to understand and follow the key processes and will also help with the audit as it can be presented to the auditor.

## ISO 9001:2015 Audit

During an audit – the auditor(s) will be looking for objective evidence that each clause in the standard has been met and complied with.

The Clauses from 4 to 10 in the standard will all be reviewed for compliance but it is also possible to state that some clauses such as the clauses relating to measuring equipment or design are 'Not Applicable' and will not require any review. These exclusions should be documented with a justification for their exclusion.

As well as reviewing all the relevant clauses there are various other things you can prepare and have in place prior to the audit:

- Completed and up-to-date management review
- Internal audit records
- Evidence of customer feedback
- Some examples of continual improvement
- Key records such as equipment calibration records should be available for review
- Evidence of compliance with applicable regulations (including recent updates to laws and regulations which affect the business)
- System for logging and tracking any issues that arise within the business
- Closure of any non-conformances and addressing of any findings from prior audits (as applicable)

Further information about the **ISO 9001** audit process and guidance for preparing for a certification audit is available at the following pages;

- [ISO 9001 Certification Guidance](#)
- [ISO Certification Guidance](#)